EDITORIAL

Manoj K. Singh
Founding Partner

Dear Friends,

The regulatory body of any country shall be the strongest body as it is responsible in taking all necessary actions in its jurisdiction to maintain the quality of a drug during its research, manufacturing and distribution. It plays an important role in running the health care system of the country. Any amendments made in acts and regulatory guidelines should be placed in the public domain to make an easy access of such amendments and guidelines to public and various stakeholders dealing with drug manufacturing.

We are pleased to present this Vol. IV Issue II of S&A – Pharma Newsletter. Through this newsletter, we aim to share recent information allied to regulatory reforms and updates from pharmaceutical sector in India as well as from foreign jurisdictions, based on information collated through research and appraisal of applicable statutory provisions.

In the present issue, we start with the draft amendments to the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020, which provide guidelines to the manufacturers selling product with magic remedies. Moving ahead, the issue discusses the recent amendments to Medical Termination pregnancy act. Further on, the issue outlines the guidelines released by ASCI on ausage of awards and rankings in healthcare Advertisements. We then inform our readers about the extension of last date for FDC manufacturers to submit applications to CDSCO. Next, the issue also discusses the notification issued by health ministry which makes marketers also liable for drug quality along with the manufacturers. Towards the end, we bring to you a write-up on NPPA revising and fixing the retail price of 17 formulations under DPCO 2013.

As always, we round-up the issue with recent healthcare updates from India, presented as a separate section under '*India HealthCare Highlights February 2020' and* a separate section from the international arena which highlights the recent regulatory updates from WHO under the heading '*WHO updates February 2020'*.

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Trust you enjoy reading this issue as well. Please feel free to send your valuable inputs / comments at newsletter@singhassociates.in

Thank you.

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Draft Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill, 2020

On February 03, 2020, the Ministry of Health and Family Welfare, Government of India, put forth a proposal to amend the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, in view of major concerns raised on implementation and effectiveness of the same.[1]

Background

The health ministry has noticed that there are major concerns regarding the effectiveness of the act; and in response the ministry has proposed that any suggestion regarding the amendment of the bill may be forwarded within 45 days from the date of issue of the notice, by email on drugsdivmohfw@gov.in or by post to Under Secretary (Drugs Regulation), Ministry of Health. All the suggestions shall be taken into consideration within the period of 45 days for finalization of the notification.

- The act shall be called the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Act, 2020, and shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.
- In the new amendment, the government has substituted a clause in section 2, for clause (a) which states that "'advertisement' means any audio or visual publicity, representation, endorsement or pronouncement made by means of light, sound, smoke, gas, print, electronic media, internet or website and includes any notice, circular, label, wrapper, invoice, banner, poster or such other documents".
- The sub clause of section 3 of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 states that Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders for "the maintenance or improvement of the capacity of human beings for sexual pleasure; or. The new amendment also includes a sub clause after sub clause 2 of section 3 which states that "after consultation with Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C of the Drugs and Cosmetics Act, 1940 in respect of Ayurvedic, Siddha and Unani system of medicines."
- In case of repeated violation, imprisonment may extend to five years with a fine up to Rs 50 lakh.
- The draft bill has also expanded the list of diseases from 54 to 78 on which the ministry prohibits any advertisements which claim to cure "any" of the 78 diseases, disorders or conditions that it has specified. The current law identifies 'magic remedy' in the form of a talisman, mantra, kavacha or any other charm which supposedly possesses miraculous powers to diagnose, cure, mitigate, treat or prevent any disease in human beings or animals or for effect or influence in any way the structure or any organic function of the body of human beings or animals.

Conclusion

The health ministry, after receiving various suggestions from different stakeholders, proposed recent amendments in order to keep pace with changing time and technology. These amendments will help the pharmaceutical companies to avoid such kind of advertisement of drugs with magic remedies.

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1 https://mohfw.gov.in/sites/default/files/Draft%20of%20the%20Drugs%20and%20Magic%20Remedies.pdf

The Medical Termination of Pregnancy (Amendment) Bill, 2020

On January 29, 2020, the Union Cabinet approved the Medical Termination of Pregnancy (Amendment) Bill, 2020, to amend the Medical Termination of Pregnancy Act, 1971. The bill requires further approval in the ensuing session of the Parliament to form a revised Act.

According to Section 3 (2) of the MTP Act, 1971, a pregnancy may be terminated by a registered medical practitioner:;

- *Where the length of the pregnancy does not exceed twelve weeks, or*
- *Where the length of the pregnancy exceeds twelve weeks but does not exceed twenty weeks. In this case, the abortion will take place, if not less than two registered medical practitioners are of opinion, that the continuance of the pregnancy would involve a risk to the life of the pregnant woman (her physical or mental health); or there is a substantial risk that if the child were born, it would suffer from some physical or mental abnormalities to be seriously handicapped***.**

The proposed **amendments** introduce the following provisions:

- For termination of pregnancy up to 20 weeks of gestation the opinion of one *registered medical practitioner* will be required, and for termination of pregnancy of 20-24 weeks of gestation opinion of two *registered medical practitioners* will be required.
- Extending the upper gestation limit from 20 to 24 weeks for special categories of women which includes *vulnerable women including survivors of rape, victims of incest and other vulnerable women* (like differently-abled women, minors) etc.
- Upper gestation limit not to apply in cases of substantial foetal abnormalities diagnosed by Medical Board. The composition, functions and other details of Medical Board to be prescribed subsequently in Rules under the Act.
- Name and other particulars of a woman whose pregnancy has been terminated shall not be revealed except to a person authorized in any law for the time being in force.

The Medical Termination of Pregnancy (Amendment) Bill, 2020 is for expanding access of women to safe and legal abortion services on therapeutic, eugenic, humanitarian or social grounds. The proposed amendments to increase upper gestation limit for termination of pregnancy for women in special category aim to strengthen access to comprehensive abortion care, under strict conditions, without compromising service and quality of safe abortion.

The amendment is in response to several petitions received by the courts seeking permission for aborting pregnancies at a gestational age beyond the present permissible limit on grounds of foetal abnormalities or pregnancies due to sexual violence faced by women. Further, the Ministry of Health and Family Welfare proposed amendments after extensive consultation with various stake holders and several ministries[1].

Note – At present most countries allow elective abortions but only a few including Canada, China, the Netherlands, North Korea, Singapore, the United States, and Vietnam permit MTP after 20 weeks. The late termination of pregnancy is legally get conflict with the viability of the foetus (where a foetus is capable of living outside the womb) and risk of maternal mortality in case of unsafe abortion or risk related to delayed abortion.

1 https://pib.gov.in/PressReleseDetail.aspx?PRID=1600916

ASCI releases guidelines for usage of Awards and Rankings in healthcare advertisements

On January 20, 2020, the Advertisement Standards Council of India (ASCI) released guidelines for usage of Awards and Rankings in healthcare advertisements, which came into force from 1st February, 2020. Awards and rankings are increasingly being used by advertisers to make superiority claims for their products and services in advertising. Consumers are sometimes misled into believing that an award or ranking which is given to a brand, product, institute or service makes it superior and /or more authentic.

Therefore, it is necessary to validate that awards and rankings used in advertising are sourced from credible, recognized, independent bodies which employ ethical processes, rigour and appropriate research so that superiority claims made by advertisers are substantiated and do not mislead consumers.

The guidelines create awareness for advertisers for appropriate usage of reference to awards or rankings in advertising; to ensure that their claims are not misleading. The guidelines will also assist the advertisers to understand the rigour required for claim substantiation and pitfalls to avoid so that their claims pass the muster with ASCI's Consumer Complaints Council (CCC).

The guidelines are applicable to all advertisers and will particularly be relevant for healthcare services and the educational sector which tend to use such superiority or leadership claims. In the health services sector, misleading claims about rankings and awards lure patients in choosing the service provider which can hamper patient health, quality of care received and result into financial losses.

Salient features of ASCI Guidelines

These guidelines are developed to guide advertisers for appropriate references to award/s or ranking/s claim/s in advertising:

1. Rankings should not be used as an alternative for consumer or scientific research or testing to substantiate the effective use or performance of service and products.
2. Awards/rankings in advertisement should clearly indicate the name of the awarding body and the month and year in which the award/ranking was pronounced to indicate the validity of award/ranking.
3. The permission/consent of the person, institution or organisation conferring the award/ranking before being used in the advertisement.
4. Awards/rankings based on surveys done in one area region/category/department cannot be extrapolated to include a larger territory (say, India, Asia, World)/overall and institution respectively.
5. To substantiate the award/ranking claim, the advertiser needs to give an undertaking that there is no commercial relationship or conflict of interest between the awarding organisation/the research agency/ jury members and the advertiser and that they are two independent entities.
6. In case of a complaint lodged at ASCI against an advertisement claiming award/ranking for a healthcare enterprise/hospital/treatment, then the concerned advertiser will be required to provide details on the protocol/process followed for conferring the award/ranking on the product/service.

About ASCI

The Advertising Standards Council of India (ASCI) is a self-regulatory council which seeks to ensure that advertisements conform to its Code for Self-Regulation, which requires advertisements to be legal, decent, honest and truthful and not hazardous or harmful while observing fairness in competition. ASCI looks into complaints across ALL MEDIA such as print, TV, radio, hoardings, SMS, emailers, internet / web-site, product packaging, brochures, promotional material and point of sale material etc. ASCI's role has been acclaimed by various Government bodies including the Department of Consumer Affairs (DoCA), Food Safety and Standards Authority of India (FSSAI), Ministry of AYUSH as well as the Ministry of Information and Broadcasting. The association with these Government bodies is to co-regulate and curb misleading and objectionable advertisements in the respective sectors[1].

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1 https://ascionline.org/images/pdf/asci%20guidelines%20for%20usage%20of%20awards_rankings%20in%20advertisements.pdf

CDSCO extends the last date to Submit Application for FDCs Manufacturers

On February 07, 2020, the Central Drugs Standard Control Organization (CDSCO) directed the manufacturers of Fixed-Dose Combination (FDCs) who are already holding the licenses from state drug licensing authority for such FDCs from before October 01, 2012, and did not submit an application to Drug Controller General of India (DCGI), are required to submit their application on or before May 30, 2020. The notification is applicable only to the manufacturers for category 'd' Fixed-Dose Combinations (FDCs) as per Kokate Committee Report.

The Prof. C. K. Kokate Committee, after holding a series of meetings had submitted its second assessment report to the Ministry of Health and Family Welfare (MoHFW) on May 27, 2016, categorizing FDCs into:

- irrational (category 'a')
- requiring further deliberation (category 'b'),
- rational (category 'c'), and
- FDCs requiring generation of data (category'd').

The committee had examined 418 applications of FDCs and found 324 FDCs as irrational while only 28 FDCs as rational. The panel had further stated that they required more data for 2 FDCs and 4 FDCs required further deliberation. It was also observed that out of the remaining 60 FDCs, 48 FDCs have already been prohibited, 11 have been declared rational and one FDC is sub-judice category (1 FDC) by the Kokate Committee which were placed in the list of these 418 applications of FDCs inadvertently.

Accordingly, the committee examined the safety and efficacy of unapproved FDCs which were licensed by state licensing authorities without due approval of DCGI. The committee requested such manufactures who are already holding the licenses from state drug Licensing authorities for such FDCs from before October 01, 2012, and did not submit an application to DCGI, to file application to DCGI well before November 22, 2019. However, with the expiry of the last date, and various representations received requesting for an extension of time, the CDSCO has decided to provide another chance to these manufacturers for category 'd' FDCs to submit their application with the date extended till May 30, 2020.

In furtherance to this, the CDSCO requested that without prejudice to the legal validity of such product licenses, all the concerned manufacturers/stakeholders are requested to submit their application along with requisite fees as specified in the Sixth Schedule of the New Drugs and Clinical Trial Rules, 2019, by May 30, 2020[1].

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1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0Ng==

Health ministry issues notification making marketers and manufactures, both liable for drug quality

The union Health and Family Welfare Ministry has come out with a notification on implementation of Drugs and Cosmetics (Amendment) Rules, 2020, which holds marketers along with the manufacturers responsible for ensuring quality and regulatory compliances of the marketed drugs in the country. [1]

Background

The Ministry of Union Health and Family Welfare, on February 13, 2020, issued a notification where shall be replaced as clause (eb) containing definition of "Marketer" which means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution.

Apart from this amendment, after Rule 83C Rule 84D and Rule 84E have been inserted in Drugs and Cosmetics Rules, 1945, to define agreement for marketing and responsibility of marketer of the drugs respectively.

The newly inserted Rule 84D containing agreement for marketing states that no marketer shall adopt any drug manufactured by another manufacturer for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution without an agreement as referred to in clause (ea) of Rule 2. The other rule 84E comprising of responsibility of marketer of the drugs states that "any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these rules."

Sub-clause (xiii) shall be inserted after sub-clause (xii) of clause (1) in Rule 96 of Drugs and Cosmetics Rules stating that a drug pack shall contain the name of the marketer of the drug and its address, in case the drug is marketed by a marketer. If the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the marketer is shown.

Note: This amended rule is known as the Drugs and Cosmetics (Amendment) Rules, 2020 and shall come into force on the 1st day of March 2021.

Conclusion

The recent amendment in the Drug and Cosmetic Act shall will prevent pharmaceutical companies from marketing drugs manufactured by another pharmaceutical company by labeling their own company name, hence preventing drug duplication. This will help in selling the original product to the public and will prevent serious adverse events associated with drug duplication.

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1 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU1OA==

NPPA fixes retail price for 17 formulations under DPCO 2013

On January 28, 2020, National Pharmaceutical Pricing Authority (NPPA) fixed the pricing of 17 formulations under Drugs Prices Control Order (DPCO) 2013.[1]

Background

In order to make the drugs accessible to general public at cost effective rates, NPPA decided to reduce the ceiling price of 17 formulations including glimepiride + metformin tablet (Rs. 4.95), telmisartan + chlorthalidone tablet (Rs. 13.28), aceclofenac + paracetamol tablet (Mytigesic Plus Rs. 3.04), diclofenac + paracetamol tablet (Inflamase Plus, Rs. 2.782), clopidogrel tablet (Rs. 6.25), metoprolol tablet (Rs. 3.03), rosuvastatin + clopidogrel capsule (Rs. 12.95), telmisartan + cilnidipine tablet (Rs. 8.19), paracetamol tablet (Rs. 3.38), amoxycillin + potassium clavulanate dry syrup (Rs. 3.27) (Genomox-CV Forte), dextromethorpran hydrobromide + chlorpheniramine maleate syrup (Re. 0.57) and paracetamol + phenylephrine hcl + diphenhydramine hcl + caffeine tablet (Rs. 3.36). The formulations which have undergone price fixation are human normal immunoglobulin.

Note:

- All manufacturers of these 17 formulations i.e. "new drug" under paragraph 2(u) of the DPCO 2013, should revise the prices of all such formulations downward not exceeding the ceiling price as specified plus goods and services taxes applicable, if any.
- The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of notification as per paragraph 24 of the DPCO 2013 which states that *"every retailer and dealer shall display the price list and supplementary price list, if any, as furnished by the manufacturer on a conspicuous part of the premises where he carries on his business"* to NPPA through IPDMS and submit a copy to state drug controller and dealers.
- The revised ceiling price is applicable only to those individual manufacturers / marketers who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO 2013 and subject to fulfilment of all the applicable statutory requirements, as laid down by the government under relevant statutes/ rules including manufacturing license permission from the competent authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.
- In case the retail price of the 17 formulations are not revised, the manufacturer shall be liable to deposit overcharged amount along with the interest thereon under the provisions of the DPCO 2013.

Conclusion

By fixing the price of these 17 formulations, NPPA has made these essential medicines affordable for the public. This will help the society in treating diseases with ease and will also provide stringent guidelines to pharmaceutical companies in price fixing and not increasing the retail price above the mentioned price limit.

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1 http://www.nppaindia.nic.in/wp-content/uploads/2020/01/English_1.pdf

India Healthcare Highlights February 2020

This segment of the newsletter shares recent information related to regulatory reforms from Healthcare and Pharmaceutical sectors in India. This segment collates information on monthly basis via conducting research and appraisal of applicable statutory provisions. Below are the highlights for February 2020.

Health Care Budget allocation in Union Budget 2020-21[1]

On February 01, 2020, the Union Minister for Finance and Corporate Affairs presented the Union Budget 2020-21 in Parliament; about Rs 69,000 crores have been allocated for Health Care, which includes Rs. 6400 crores for Prime Minister Jan Arogya Yojana (PMJAY). The Finance Minister also stated that there are more than 20,000 empaneled hospitals under PM Jan Arogya Yojana (PMJAY) and government is planning more empaneled hospitals under PMJAY in Tier-2 and Tier-3 cities for poor people. It has been proposed to set up Viability Gap funding window for setting up hospitals in the PPP mode. In the first phase, those aspirational districts will be covered where presently there are no Ayushman empanelled hospitals. This would also provide large scale employment opportunities to youth. Proceeds from taxes on medical devices would be used to support this vital health infrastructure. The Finance Minister also announced the launch of "TB Harega Desh Jeetega campaign" towards government's commitment to end tuberculosis by 2025. The Minister for Finance and Corporate Affairs also announced expansion of Jan Aushadhi Kendra Scheme to all districts offering 2000 medicines and 300 surgical by 2024.

Indian institute IVRI releases live attenuated Classical Swine Fever Vaccine (IVRI-CSF-BS) from indigenous strain of virus[2]

On February 03, 2020, the Indian Veterinary Research Institute (IVRI), Izatnagar under Indian Council of Agricultural Research (ICAR) has released the live attenuated **Classical Swine Fever Vaccine** (CSF-BS) Technology by attenuating an indigenous virulent CSF virus in cell culture. **Classical Swine Fever** is one of the most serious diseases in pigs causing high mortality with annual loss of approx. Rs.4.299 billion. A lapinized CSF vaccine (Weybridge strain, UK) is being used in India since 1964 for controlling the disease. The vaccine is produced by sacrificing large number of rabbits for each batch. In order to do away with sacrificing of rabbits and increase the productivity, IVRI had earlier developed a cell culture CSF vaccine by adapting the lapinized vaccine virus in cell culture. The technology has been transferred to M/s Indian Immunologicals, Hyderabad and Government of Punjab during 2016 and 2018, respectively. IVRI has further developed a new CSF Cell Culture Vaccine by attenuating an indigenous virulent CSF virus in cell culture. The vaccine virus has very high titre and lakhs of doses can be produced very easily in cell culture and country's requirement can be easily fulfilled using this new vaccine. The new vaccine will be part of the government's One Health Initiative and result in huge savings as it will nip the spread of the virus at animal stage so that it does not pass on to the human population. This new vaccine will be the most economical CSF vaccine costing around less than Rs 2/- per dose as against Rs 15-25/- of lapinized CSF vaccine and Rs.30/dose (approx) for an imported Korean vaccine being used in the country. Besides, the new vaccine gives immunity for two years as compared to 3 to 6 months protection under the vaccines currently being used. The patent application for the new vaccine, which has been developed by a team of IVRI scientists, is already submitted. The vaccine is safe, potent, does not revert to virulence and provides protective immunity from day 14 of the vaccination till 24 months studied so far. The vaccine has been tested on around 500 pigs at multiple locations.

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1 https://pib.gov.in/PressReleseDetail.aspx?PRID=1601447

2 https://pib.gov.in/PressReleseDetail.aspx?PRID=1601778

DCGI defines all medical devices as drugs to mandate their safety and quality standard approval before drug approving authority[3]

The Union Health Ministry, on February 11, 2020, through a gazette notification defined all medical equipment/ devices used on humans or animals as "drugs" with effect from April 01, 2020. This notification mandates all medical devices to pass specific safety and quality standards from drug approving authority before they are introduced in the India market. At present, only 23 medical devices are regulated under the Drugs & Cosmetic Act, 1940. However, with the new announcement, all medical devices used on humans or animals have been included as "drugs" under sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act.

This includes an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or an accessory, intended by its manufacturer to be used especially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of: *"(i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (vi) control of conception."*

Further, since this notification will cover all Medical Devices, the provisions in Medical Device Rule, 2017, will be automatically applicable to them without individual or class notification which is not the proposed transition scheme by way of registration.

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3 http://www.egazette.nic.in/WriteReadData/2020/216073.pdf

WHO Pharma Highlights February 2020Arnika Sharma

This segment of the newsletter focusses on sharing the recent regulatory reforms and updates on Healthcare and Pharmaceutical domain from World Health Organization (WHO). This segment collates information periodically via conducting research and review of pharmaceutical updates from the WHO. Below are the highlights for the month of February 2020:

Four Countries in Africa licensed an Ebola vaccine as preventive measure[1]

The Democratic Republic of the Congo (DRC), Burundi, Ghana and Zambia have licensed an Ebola vaccine, just 90 days after World Health Organization (WHO) prequalification. Registration of the vaccine is expected in additional countries in the coming weeks. WHO accelerated the licensing and roll-out of the Ebola vaccine by certifying that it met the organization's standards for quality, safety and efficacy in its fastest vaccine prequalification process ever.

WHO accelerates research on new coronavirus[2]

WHO convened a global research and innovation forum to mobilize international action in response to the new coronavirus (2019-nCoV). The forum, held on 11-12 February in Geneva, was organized in collaboration with the Global Research Collaboration for Infectious Disease Preparedness.

WHO and FIND formalize strategic collaboration to drive universal access to essential diagnostics[3]

The World Health Organization (WHO) and the Foundation for Innovative New Diagnostics (FIND) announced that a memorandum of understanding has been signed by the two organizations to formalize a strategic collaboration that will strengthen diagnosis in resource-poor countries by closing major diagnostic gaps at country level and bolstering disease surveillance which will inform public health initiatives and enhance outbreak preparedness and response.

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1 https://www.who.int/news-room/detail/14-02-2020-four-countries-in-the-african-region-license-vaccine-in-milestone-for-ebola-prevention

2 https://www.who.int/news-room/detail/06-02-2020-who-to-accelerate-research-and-innovation-for-new-coronavirus

3 https://www.who.int/news-room/detail/10-02-2020-who-and-find-formalize-strategic-collaboration-to-drive-universal-access-to-essential-diagnostics

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